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| APPLICATION NO.           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
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| 10/549,731                | 10/25/2006  | Stefan Leyen         | DNAG-310                      | 1384             |
| 24972                     | 7590        | 03/23/2009           |                               |                  |
| FULBRIGHT & JAWORSKI, LLP |             |                      | EXAMINER                      |                  |
| 666 FIFTH AVE             |             |                      | STEWART, JASON-DENNIS NEILKEN |                  |
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|                           |             |                      | ART UNIT                      | PAPER NUMBER     |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/549,731

**Applicant(s)**

LEYEN ET AL.

**Examiner**

JASON-DENNIS STEWART

**Art Unit**

3738

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

The following is a Final Office action in response to communications received on 12/19/2008. Claims 35 and 45 are amended. Claims 35-45 are currently pending and addressed below.

#### ***Response to Amendment***

The amendments to the claims are sufficient in overcoming the U.S.C. 112, 2nd paragraph rejections of the previous Office action.

#### ***Drawings***

The new drawing (Fig. 5) was received on 9/18/08. This drawing is not acceptable because the use of "radius" is not clear since the term defines a line and the drawing submitted is showing the line extending from some center point of space which Applicant cannot refer to. It is not clear if Applicant means radius to define the depth of the notch from the inner surface of the cup. Even with the amendments to claim language, it is still necessary for Applicant to clarify in the drawing what length is meant to be the notch radius.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 35-41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. (6,676,704) further in view of McLean et al. 2004/0054418.
3. Regarding Claims 35-38, Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, Bunz does not disclose surface semicircular depressions arranged circumferentially on the outside of the sliding cup.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, ll. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, ll. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the sliding cup of the sandwich insert of Bunz with the undulating

depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, ll. 23-25).

Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a metal shell around the plastic covering.

McLean discloses a hip prosthesis comprising a metal shell with a polyethylene liner adapted to fit tightly in the shell (paragraph 3).

It should be noted that the use of plastic liner inside or metal shells is widely known and practiced in the art. It would have been obvious to one of ordinary skill in the art to modify the device of Bunz with a metal shell in order to provide articulating surface for a femoral head as disclosed by McLean (paragraph 3).

4. Regarding Claim 39, Bunz illustrates a sliding cup (1) having a stepped structural form on its outside (fig. 2).
5. Regarding Claim 40, Bunz illustrates the plastic covering embracing the sliding cup at its pin end (fig. 2).
6. Regarding Claim 41, Bunz illustrates a collar of the plastic covering 5 that rests on the upper side of the sliding cup and covers almost half of the upper edge (fig. 2).
7. Regarding Claim 43, Bunz in view of Pope discloses the invention as claimed and as discussed above. However, Bunz as modified by Pope do not disclose an eccentric relationship between the inner and outer form of the sliding cup.

McLean et al. discloses an eccentric relationship between the inner surface 30 and the outer surface 26 of an articulating surface shell in order to improve migration and other properties of the prosthesis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope with the eccentric relationship of McLean in order to optimize articulating wear properties of the sliding cup relative to the femoral head.

8. Regarding Claim 44, Bunz in view Pope and further in view of McLean discloses the invention as claimed and discussed above, however Bunz does not positively recite the range claimed in Claim 34. It has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, **see MPEP 2144.05, Part II, section A**.

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. '704 in view of McLean et al. 2004/0054418 and further in view of Teinturier (5,041,140).

Bunz in view of Pope in view of McLean discloses the invention as claimed and as discussed above. However, Bunz in view of Pope does not disclose a press fit between the sliding cup and the plastic covering.

Teinturier teaches a press fit between a plastic cup 42 and a metal shell in order to allow the acetabulum unit to adapt to deformations of the skeleton and adapt to them (col. 4, ll. 59-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sliding cup of Bunz in view of Pope by press fitting it into the plastic covering as taught by Teinturier in order to allow for deformation of the skeleton by the hip prosthesis.

10. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz et al. WO 01/05338 in view of Pope et al. (6,676,704).

11. Bunz discloses a hip joint prosthesis comprising an inner sliding cup made of ceramic material that is surrounded on its outside by a plastic covering (abstract).

However, although implied, Bunz does not disclose surface "structuring". It should be noted that the term "structuring" does not define a particular structure; however, the Examiner is examining this limitation as best understood.

Pope discloses a substrate for attachment to a femoral head and an acetabular comprising of spherical segment depressions with a diameter from .001 in. up to .750 in. (col. 43, ll. 15-35), undulating in section, and circumferentially arranged (fig. 3c) for the purpose of creating a mechanical interlock between adjacent layers of the hip prosthesis (col. 41, ll. 23-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the sliding cup of the sandwich insert of Bunz with the undulating depressions of Pope in order to achieve a mechanical interlock as taught by Pope (col. 41, ll. 23-25).

***Response to Arguments***

12. Applicant's arguments filed 12/19/08 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the inventions of Bunz and Pope. The Examiner respectfully disagrees. The device of Pope has disclosed a method of interlocking layers of an orthopedic implant. It uses a method that is substantially equivalent to that claimed by the Applicant because of the use of undulations on a surface locking to depressions on a facing surface. Regardless of the location of the two surfaces outside of their relation to each other, this method solves the same problem as that of the Applicant which is achieving a mechanical interlock. Substituting the interlock method of Bunz with the interlocking method of Pope would have been obvious to one of ordinary skill in the art as both of the methods of achieving mechanical interlock were known and used in the art at the time of Applicant's invention. This is not an example of impermissible hindsight.

13. Applicant also argues that Pope teaches away from the use of the materials of Bunz. The Examiner respectfully disagrees. Pope's arguments refer to materials being used at an interface between a femoral head component and an acetabular bearing surface which would be subject to a completely different magnitude of forces because of the articulation between the two components. These arguments do not pertain to the use of layers in an acetabular insert.



***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JASON-DENNIS STEWART** whose telephone number is (571)270-3080. The examiner can normally be reached on **M-F (alt Fridays off) 7:30-5:00 EST**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738